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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/784,646 | 02/23/2004 | Joseph P. Errico | F-269 | 8184 |
| 530 | 7590 | 12/24/2009 | EXAMINER | |
| LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090 | | | PELLEGRINO, BRIAN E | |
| ART UNIT | PAPER NUMBER | | | |
| | | | 3738 | |
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| 12/24/2009 | PAPER | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--|--------------------------------------|
| Office Action Summary | Application No. 10/784,646 | Applicant(s) ERRICO ET AL. |
| | Examiner Brian E. Pellegrino | Art Unit 3738 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on **24 September 2009**.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) **1,3-12 and 14-21** is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) **1,3-8,10,11,15-18,20 and 21** is/are rejected.
 7) Claim(s) **9,12,14 and 19** is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 9/24/09
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/24/09 has been entered.

The following Office Action contains rejections to previously allowed and/or previously objected-to-as-allowable material as indicated in Office Action mailed 6/24/09. Accordingly, the following action has been made Non-Final. A newly discovered reference to Paponneau (2003/176925) in view of Applicant's submission of an information disclosure statement in copending application on 9/24/09 prompted the new ground(s) of rejection presented in this Office action.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,4,5,10,11,15-18,20,21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grunberg et al. (WO 02/71986) in view of Paponneau (2003/176925).

Figs. 4a,4b show apparatus for distracting intervertebral space comprising a shaft within the sides (402,404) with at least two distal extensions (407,409) coupled to the shaft. The distal extensions have a fixed dimension from one another in the same plane, but the intermediate portions of the extensions move toward and separate via the distractor mechanism **416** in the intermediate location. It can also be seen that there is a first trial half **202** with pins **410** coupled at the distal end of the extensions and a second bifurcated trial plate fixed thereto to the plates, page 18. Please note the Examiner is not giving any special definition to the term "fixed" as it is being interpreted to be in a non-movable location, Grunberg discloses that the pins keep the plate halves in a fixed location, page 18, 1st paragraph. It can be seen that in the intermediate portion between the extensions is a distraction mechanism **416** having multiple pins extending through links such that forward and backward movement can occur. However, Grunberg et al. fail to disclose the intervertebral bifurcated halves pivot or allow for separation. Paponneau teaches (Fig. 5) an intervertebral bifurcated prosthesis with halves **24,26** that pivot. It would have been obvious to one of ordinary skill in the art to use pivotable intervertebral halves as taught by Paponneau with the intervertebral system of Grunberg et al. such that it provides the surgeon the ability to adjust the apparatus between the vertebrae in the correct orientation and ability to have relative motion.

Regarding claim 10, it can be seen the distractor mechanism includes a pin that can move proximally and distally to increase and decrease the separation between the intermediate portions of the extensions to act as a fulcrum. It can also be seen there is a bifurcated trial with two halves **202** coupled to the distal extensions. The examiner is

interpreting the claimed elements "bifurcated trial" in this way: two split halves capable of being inserted into the intervertebral space. Claims in a pending application should be given their broadest reasonable interpretation. *In re Pearson*, 181 USPQ 641 (CCPA 1974). See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054,1055. The external shape is capable of "approximating" the external disc shape of the artificial intervertebral disc. Regarding claims 4,5 the trial halves have a smooth outward facing surface, see Fig. 7. Regarding claim 11, please note the functional limitation "biased" carries no weight in the absence of any distinguishing structure. Regarding claim 16,18,20 there is a control device **414** or knob coupled to the apparatus that can be rotated. With respect to claim 17, it can be interpreted that hinge structure (416) is a control device to maintain separation of the trial halves.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grunberg et al. in view of Paponneau as applied to claim 1 above, and further in view of Baumgartner (5370697). Grunberg et al. in view of Paponneau is explained above. However, Grunberg et al. as modified with Paponneau fail to teach a dome outer surface on the implant. Baumgartner shows (Fig. 5) a vertebral contact element **44** having a resting shape of a dome convexly extending from an orthopedic device **2**. It would have been obvious to one of ordinary skill in the art to utilize a dome outer surface on the implant as taught by Baumgartner with the apparatus of Grunberg et al. as modified with Paponneau such that it can be placed within the vertebrae's contour.

Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grunberg et al. (WO 02/71986) in view of Paponneau as applied to claim 1 above, and

further in view of Ripple et al. (4566466). Grunberg et al. in view of Paponneau is explained supra. However, Grunberg et al. as modified by Paponneau fail to teach markings for sizing. Ripple et al. teach (Figs. 6,7) markings for sizing a disc to be implanted. It would have been obvious to one of ordinary skill in the art to use markings as taught by Ripple et al. with the apparatus of Grunberg et al. such that the proper implant can be determined for the patient. It is well known in the art to use markings on shafts and would have been obvious to one of ordinary skill in the art to incorporate markings on a shaft of Grunberg et al. It would have been an obvious expedient to modify the dimensions of the disc size, since using 13mm-20mm would only involve routine skill in the art of a surgeon in estimating the intervertebral space and the proper size of the implant to be placed therein. One of ordinary skill in the art clearly can optimize the sizes as taught by Ripple or the claimed range of 13-20mm in claim(s) 8 because both apparatus perform the same function of finding the appropriate size for the patient and would have predictable results on filling the space between vertebrae of a patient.

Allowable Subject Matter

Claims 9,12,14,19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738